CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Comments submitted by European Union

Agenda Item 5(a) **Section 2 of the 2024 JMPR Report**

Report on items of general consideration arising from the 2024 JMPR meeting

European Union Competence
European Union Vote

The European Union (EU) would like to provide the following comments on section 2 (general considerations) of the 2024 JMPR Report:

2.1 Developments in dietary exposure methodology for pesticide residues in foods

The EU welcomes the join efforts from CCPR and JMPR to address the concerns from Codex Members and observers discussed in CCPR55.

At the 2024 JMPR meeting, a comparison was conducted between dietary exposure estimates derived with IEDI methodology and GECDE estimates to assess GECDE's conservatism. The focus was on three pesticides—boscalid, iprodione, and piperonyl butoxide—highlighted in the 2023 report for their high variance between GECDE and IEDI estimates. Using 61 surveys from the FAO/WHO GIFT database, the assessment incorporated individual consumption data and 2023 STMR data. According to JMPR, the findings indicated strong agreement between individual consumption-based exposure estimates and GECDE-mean (R2=0.95), however, the EU would like to highlight that the data showed only moderate correlation between the GECDE-high and the P97.5 of individual dietary exposure (GECDE-high vs. P95 R2=0.77; GECDE-high vs. P97.5 R2=0.67).

If the intention of the calculation of the correlation coefficient was to assess the level of conservatism and to validate the GECDE-high methodology the EU considers that this analysis as insufficient and more efforts would be needed in a proper validation of the methodology.

For increasing transparency of the analysis of the level of conservatism, it would be desirable to provide the following additional information:

- A detailed analysis per pesticide (instead of presenting the overall results for all three pesticides in one chart);
- Further analysis for the calculations for pesticide/country/cohorts for which the results between high percentile derived using food consumption data from individuals and GECDE-high. It is unclear what are the main reasons for differences observed between the two calculations
- Further information on the drivers of the GECDE-high calculations (key foods driving exposure calculations), together with the respective percentile of consumption used in the exposure calculation (P97.5 P95 or an alternative percentile) and the respective diets (country/cohorts);
- Additional information on the frequency of eaters (proportion of eaters within a survey) for the commodities driving the GEDE calculations (P97.5 or alternative percentile).
- Additional details on the calculations of the P97.5 of individual dietary exposure, which was used as a reference for deriving the correlation coefficients.
- Considering that for some of the pesticide/country/cohort combinations, the exposure calculated with GECDE mean and GECDE high exceeded the ADI, JMPR should provide further information on how GECDE calculations could be

further refined (e.g. whether additional processing data could be useful to refine the GECDE calculations; if so, commodities should be reported for which PF could potentially have a significant impact on the outcome of the exposure calculations).

- Other specific clarifications:
  - For boscalid, it is unclear if the GECDE calculations also covered residues in rotational crops. If so, information should be provided on whether the frequency or likelihood of residues in rotational crops were considered in the exposure calculations.
  - Has JMPR considered the toxicological profiling for the three pesticides used in the 2024 to decide which population subgroups would be relevant?
  - Explanations are needed on the units of the x- and y-axis of Figure 1 presented in the JMPR report.

The JMPR used high percentiles (P97.5 and P95) from exposure distributions across countries/cohorts, akin to the new EFSA PRIMo 4 methodology for calculating High-Risk Percentiles (HRP) of chronic exposure. However, the EU would like to clarify that for PRIMo 4 methodology it has not yet decided which percentile will be used for regulatory decisions.

The analysis so far has only covered three pesticides, indicating the need for further study. The long-term dietary exposure calculations presented in chapter 4.3.2 of JMPR Report 2024 show an important number of ADI exceedances when the exposure was calculated GECDE mean and GECDE high. Therefore, the conclusions reached with the pesticides included in the analysis might not be representative.

The EU welcomes the JMPR proposal of sharing their calculation tool to familiarize Codex members with the methodology and requests the possibility of sharing this tool with other interested parties.

Overall, the EU supports the proposal of JMPR to develop a tool including all relevant inputs for GECDE calculations. However, further validation is needed, in particular for plant-based foods, as past work focused only on animal products. The EU suggests more detailed disclosure from JMPR on GECDE calculations and associated protective levels. Discussions are needed to have a clear view on the appropriatness of the model's transition, to refine risk assessments and decide procedures if the new methodology leads to ADI exceedance. In this sense, the EU would like to propose, the establishment of a dedicated electronic working group in order to coordinate risk management and risk assessment perspectives and further develop an implementation plan.

Ongoing work is under development at EU level regarding long-term exposure methodology and reviewing the EFSA PRIMo model.

Annex 10. Dissenting opinion to Section 2.1

There is an allusion to pesticide residue experts that expressed their dissent against Section 2.1. However, there is no information as to what percentage of the total experts they represent and whether they are WHO or FAO experts – given the different roles of these organisations in JMPR. For the sake of transparency, it is important that CCPR be informed of the nature of the discussion that led to divergent views among JMPR experts.

2.2 Consideration on recommendation of group maximum residue limits for pulses

JMPR recommended that for future assessments, it would be desirable to have field trial data for both Phaseolus and Vigna genera.

The EU supports the JMPR recommendation of providing separate residue trials when there is evidence that residues in the harvested crop are significantly different in Phaseolus and Vigna beans.

The EU would appreciate to have access to the preliminary comparative analysis to get a better understanding which PHIs are expected to lead to different results, as both good agricultural practices assessed for acetamiprid had rather long PHIs (28 and 42 days).

In the EU, the MRL on dry beans (code 300010 in Annex I of Regulation (EC) No 396/2005) cover both species Phaseolus and Vigna.

2.3 Extrapolation of recommendations for tomato and pepper to eggplants (subgroup)

In 2024, JMPR reviewed the GPC's assessments, considering factors such as dietary exposure, GAP descriptions, residue trial representativeness, and residue/metabolite definitions. They found that some GPC MRL proposals did not align with JMPR's standard practices. While JMPR appreciated GPC's efforts to identify compounds for extrapolation, they suggested that future submissions be coordinated through the CCPR Working Group on Priorities for efficiency.

The EU supports JMPR's recommendation, emphasizing that JMPR's role in advising CCPR on toxicological values, MRLs, and dietary risk assessments is crucial and cannot be replaced by observers or other parties.

2.4 Transition from commodity of meat to commodity of muscle and fat

In 2024, CCPR completed the update of the Classification of Food and Feed (CXA 4-1989), specifically revising Class B for primary animal-origin food commodities. This revision introduces new definitions for "meat," "muscle," "fat," and "edible offal." The JMPR agreed to gradually update commodity definitions during pesticide reviews, meaning the same Codex code will temporarily apply to different commodity descriptions.

JMPR committed to ensuring that for previously assessed fat-soluble substances, MRLs, STMRs, and HRs for meat are based on residues in muscle, not fat.

The new Codex classification aligns with the EU food classification, allowing new Codex MRL proposals for muscle to be adopted in the EU without recalculation, provided there are no EU reservations.

To prevent confusion, the EU proposes adding a suffix to Codex MRLs and codes derived under the old classification to indicate they relate to the previous commodity descriptions.

In addition, for the substances assessed by JMPR in 2024 and for which commodity definitions were updated, in some cases JMPR re-performed a dietary burden calculation using the most recent methodology (hexythiazox, etofenprox, fipronil) while in other cases the dietary burden was not updated (cyproconazole, flubendiamide). The EU would like to ask JMPR that, as the model for dietary burden calculation has changed in 2017 (FAO manual 2016, 3rd edition), a new dietary burden calculation should be performed for all pesticides which are subject to a re-evaluation for MRLs in animal products according to the current methodology, and where appropriate, to derive updated MRL proposals.

2.5 Interpretation of use patterns for targeted applications

The EU supports the JMPR recommendation on the development of guidelines for conducting field trials for spot treatment uses, considering that precision agriculture will play an important role in reducing the use of pesticides, with positive consequences for the environment. However, the consumer safety aspect is an important element that needs to be sufficiently addressed as well, and therefore it is essential to develop guidelines for consumer risk assessment for this type of uses.

2.6 Update of the pesticide residues in food: guidance document for WHO JMPR monographers and reviewers

The EU welcomes the WHO guidance document for monographers and reviewers and requests to JMPR to launch a broader commenting phase including risk assessors in Codex member countries beyond the WHO Core Assessment Group. Experience from other bodies could help to further increase the quality of the document.

2.7 Strategy and timing for JMPR re-evaluation of dithiocarbamates

The EU welcomes the information included in the JMPR report on the proposed re-evaluation in three consecutive phases of the five notified dithiocarbamates. Considering the importance and the complexity of the review it is essential that the dossiers submitted for the different phases need are fully completed and of high quality.

Since the last comprehensive toxicological assessment dates to 1993 (last periodic review for the full group of dithiocarbamates), and 2004 (assessment of propineb) and many of the existing CXLs for dithiocarbamates are more than 25 years old, the review of CXLs should be performed with high priority.

A recently performed review of dithiocarbamates at EU level is available[1].

2.8 Linear and non-linear toxicokinetics guide progress update

The EU welcomes the completion of the first draft of the guidance document on the assessment and interpretation of non-linear toxicokinetics, prepared by the dedicated EWG of JMPR. However, the EU would like to note again, as it was done at CCPR 55, that more detailed information on the content of the guidance should be provided, including information whether the draft guidance will be open for commenting.

2.9. Data on pesticide metabolites that are also commodity chemicals

The EU agrees that submission of a comprehensive toxicological data set for commodity chemicals (i.e. low molecular weight and less specific metabolites), including data from peer reviewed literature and studies generated by other pesticide producers or for other substances than pesticides (biocides, veterinary medicinal products, other chemicals) to JMPR is essential. The EU considers therefore appropriate to provide more specific instructions in the guidance document for WHO JMPR monographs and reviewers and to develop specific instructions for data submitters as suggested in the framework of the EWG on enhancement of work of CCPR and JMPR.

[1] Review of the existing maximum residue levels for dithiocarbamates according to Article 12 of Regulation (EC) No 396/2005. https://www.efsa.europa.eu/en/efsajournal/pub/7987

For pesticide assessments at EU level, the applicant is requested to provide information whether the active substance and its metabolites has been assessed under other regulatory contexts and should inform on the availability of additional studies.

The EU would like to reiterate its recommendations from last year that sponsors/manufacturer of pesticides are invited to consult metabolism databases, such as the MetaPath for identification of metabolites that could be also derived from other active substances and get in touch with the manufacturers to get access to the toxicological data for the relevant metabolites. Another recommended source of information is OpenFoodTox, currently under update, as well the OECD QSAR toolbox where additional databases (e.g. IUCLID REACH dossiers) are available.

2.10. Efficiency of JMPR resources

Besides the continued warnings (2015, 2018, 2019, 2023) on the importance of submission of high-quality dossiers, in 2024, JMPR again received incomplete dossiers for periodic reviews and new active substances[2] or dossiers for new active substances with a limited use pattern with residues at the limit of quantification.

The EU supports the future prioritization of dossiers by JMPR. The EU suggests that in addition, detailed criteria should be elaborated to consider deletion of existing CXLs within a defined period, if sponsors of substances scheduled for the periodic review programme do not submit complete dossiers as agreed in the work programme. This would be on the interest of using JMPR resources efficiently and to ensure that periodic reviews of CXLs are not further delayed.

Agenda Item 5(b) **Section 3 of the 2024 JMPR Report**

Report on responses to specific concerns raised by CCPR arising from the 2024 JMPR meeting

General comments

The EU would like to inform CCPR Members that the CXLs that were adopted by the 47th Session of the Codex Alimentarius Commission, and for which the EU had not introduced reservations during CCPR55, have now been established in the EU.

Additionally, the EU started a review of reservations made in the past due to ongoing assessments in the EU, to assess whether they could be lifted taking into account the outcome of the EU assessments.

It is an EU policy to propose a Commission Regulation for inclusion of Codex MRLs (CXLs) into EU legislation provided that:

- the EU sets MRLs for the commodity under consideration;
- the current EU MRL is lower than the CXL.

The EU will make reservations to the advancement of the proposed Codex MRLs during the discussions on the specific substances:

- if the proposed CXL is not safe for European consumers[1], and/or
- if toxicological data are not available at EU level or are available but not yet assessed at EU level, and/or
- if the proposed CXLs are not sufficiently supported by data as required according to the FAO manual or other agreed requirements, and/or
- if the residue definition set by JMPR is incompatible with the residue definition set at EU level, and/or
- if the CXL is not acceptable to the EU with respect to areas such as supporting data, extrapolations, as well as environmental issues of global nature in accordance with WTO rules.

[1] Including an assessment that the Codex residue definition ensures an equivalent level of protection.

Additionally, the EU notes that in several cases, details of the dietary burden calculations and TTC calculations are not published in the JMPR report, whereas it would be beneficial. Given that the JMPR report is already very long in print, maybe the calculations could be made accessible in an electronic format via a link included in the JMPR report.

[2] such as chlorpyrifos for periodic review and fluazinam for new compound assessment

Agenda Item 6.1 **CX/PR 25/56/5**

MRLs for pesticides in food and feed (at Steps 7 and 4)

Chlormequat (15)

The EU **supports** the advancement of the proposed draft MRLs for the following commodities:

- **Barley**
- **Group of avian fats**
- **Group of avian muscle**
- **Group of milks**

The EU **introduces a reservation** to the advancement of the proposed draft MRLs for the following commodities:

- **Group of avian, edible offal of**
- **Group of eggs**
- **Group of edible offal (mammalian)**
- **Group of mammalian fats (except milk fat**
- **Group of muscle (from mammalians other than marine mammals)**

As noted by the EU at the 54th meeting of the CCPR in 2023, for these MRLs the result of the feeding study was rounded up to a higher MRL than necessary. Therefore, the EU invites JMPR to review these Codex MRL proposals.

Chlorpyrifos (17)

For the good use of JMPR resources, the EU regrets that the dossier submitted to JMPR was insufficient to perform a toxicological evaluation, despite a request from the sponsor at the 53th meeting of the CCPR in 2022 to maintain chlorpyrifos on the periodic review schedule for the 2024 JMPR. The EU recommends that chlorpyrifos would be moved to table 1 of CX/PR 25/56/5 "List of pesticides where MRLs have been deleted by CAC and for which no MRLs have been proposed".

Ethoxyquin (35)

The EU **supports the proposed withdrawal** of the MRLs for the following commodities:

- **Pears**

The EU recommends that ethoxyquin be moved to table 1 of CX/PR 25/56/5 "List of pesticides where MRLs have been deleted by CAC and for which no MRLs have been proposed" (unsupported substances).

Folpet (41)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities:

- **Bananas**
- **Barley**
- **Group of avian muscle**
- **Group of avian fats**
- **Group of avian, edible offal of**
- **Group of edible offal (mammalian)**
- **Group of eggs**
- **Group of mammalian fats (except milk fats)**
- **Group of muscle (from mammals other than marine mammals)**
- **Group of milks**
- **Wheat**
- **Wine grapes**

The current EU residue definition for enforcement, which is wider and includes phthalimide, is not compatible with the one derived by JMPR.

In addition, there is an ongoing assessment of an import tolerance at EU level for bananas.

Maleic hydrazide (102)

The EU notes that the MRLs proposed for withdrawal are based on GAPs in EU Member States, for which sufficient data has been made available at EU level. The EU would like to **ask to retain the existing CXLs under the 4-year rule** so that the necessary data could be submitted to JMPR for evaluation. The EU notes that in March 2025, the Manufacturer committed to supply additional data to allow for the JMPR assessment to continue in 2026 and requested that the MRLs remain under the 4-year rule.

Phosmet (103)

The EU **supports the withdrawal** of the MRLs for the following commodities:

- **Apricots**
- **Cotton seed**
- **Grapes**
- **Group of citrus fruit**
- **Group of pome fruits**
- **Group of tree nuts**
- **Meat (from mammals other than marine mammals)**
- **Milks**
- **Nectarine**
- **Peach**

The EU **introduces a reservation** to the advancement of the proposed draft MRLs for the following commodities:

- **cranberries**
- **potatoes**

A risk to EU consumers was identified (ARfD exceedances: 987% in blueberries, 769% in potatoes). For potatoes, the residue trials were conducted with an LOQ of 0.05 mg/kg, which is not sufficiently low to exclude a consumer health risk in EU.

The EU **opposes** the advancement of the proposed draft MRL for the following commodity:

- **blueberries**

JMPR identified an acute risk to consumers (650% of ARfD set by JMPR, 10135% of ARfD set in the EU). In addition, the existing CXL for blueberries should also be withdrawn.

Permethrin (120)

The EU requests withdrawing the existing Codex MRLs related to pesticide use, most of them derived 30 years ago, since the last complete evaluation was 25 years ago, in 1999.

Permethrin should be moved to table 1 of CX/PR 25/56/5 “List of pesticides where MRLs have been deleted by CAC and for which no MRLs have been proposed”.

Prochloraz (142)

The EU **introduces a reservation** to the advancement of the proposed draft MRLs for the following commodities:

- **Avocado**
- **Barley**
- **Group of avian, edible offal of**
- **Group of avian fat**
- **Group of avian muscle**
- **Group of edible offal, mammalian**
- **Group of eggs**
- **Group of mammalian fats (except milk fats)**
- **Group of milks**
- **Group of muscle (from mammals other than marine mammals)**
- **Oats**
- **Rye**
- **Triticale**
- **Wheat**

The EU considers that the TTC approach should only be used for minor metabolites, not for BTS 44595 which is a major metabolite in ruminant tissues and the predominant metabolite in many crops, including cereal grains.

Moreover, the EU would like to ask that for transparency purposes, the exposure calculations for metabolites assessed according to the TTC approach would be published, e.g. in a separate Annex to the JMPR report.

In addition, an exceedance of the ARfD for avocadoes was identified for EU consumers (585%).

Lambda-cyhalothrin (146)

Methoprene (147)

The EU **introduces a reservation** to the advancement of the proposed draft MRLs for the following commodities, due to the lack of toxicological data evaluated at EU level:

- **Group of avian, edible offal of**
- **Group of avian fats**
- **Group of avian muscle**
- **Group of edible offal (mammalian)**
- **Group of eggs**
- **Group of mammalian fats (except milk fats)**
- **Group of milks**
- **Group of muscle (from mammals other than marine mammals)**
- **Tree nuts**

Propiconazole (160)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities based on the lack of data on the magnitude and toxicity of metabolites expected in plant and animal products that need to be considered in the dietary risk assessment. In the EU assessment, the toxicological data were found insufficient to conclude on the genotoxicity potential and the general toxicity of some of the metabolites.

- **Group of avian, edible offal**
- **Group of avian fats**
- **Group of avian muscle**
- **Group of edible offal (mammalian)**
- **Group of eggs**
- **Group of mammalian fats (except milk fats)**
- **Group of milks**
- **Group of muscle (from mammals other than marine mammals)**

The EU notes that an assessment strategy for triazole derivatives metabolites (TDMs) is applicable in the EU. Residue definitions for risk assessment and toxicological reference values have been revised. The EU notes that an assessment for TDMs has not been carried out for propiconazole.

Buprofezin (173)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities:

- **Group of avian, edible offal**
- **Group of avian fats**
- **Group of avian muscle**
- **Group of edible offal (mammalian)**
- **Group of eggs**
- **Group of muscle (from mammals other than marine mammals)**
- **Group of mammalian fats (except milk fats)**

An increase of the existing limit of quantification for products of animal origin seems unnecessary based on the technical development of analytical methods.

Hexythiazox (176)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities:

- **Cane berries, subgroup of**

The same GAP assessed as an import tolerance in the EU resulted in a lower MRL of 3 mg/kg. Based on further analysis of the data used by JMPR, once the JMPR evaluation is available, this reservation could be revised.

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Group of avian muscle**
- **Group of avian, edible offal of**
- **Group of avian fat**
- **Group of edible offal, mammalian**
- **Group of eggs**
- **Group of mammalian fats (except milk fats)**
- **Group of milks**
- **Group of muscle (from mammals other than marine mammals)**
- **Hops**

The EU **notes** that the formation of the cyclohexylamine metabolite should be considered in potential future evaluations for extensions of uses in leafy crops.

The EU **notes** that the code for hops included in the JMPR report is not updated.

Etofenprox (184)

The EU **supports** the advancement of the proposed draft MRLs for the following commodities:

- **Group of avian, edible offal of**
- **Group of avian fats**
- **Group of avian muscle**
- **Group of edible offal (mammalian)**
- **Group of mammalian fats (except milk fats)**
- **Group of muscle (from mammals other than marine mammals)**
- **Group of milks**
- **Rice, husked**

The EU would like to note that the MRLs for avian product are based on metabolism studies, and to inform that a feeding study in poultry is available. A feeding study is in general the preferred basis for deriving MRL proposals for animal products.

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities:

- **Group of eggs**

The calculation of the MRL leads to a value of 0.07 mg/kg. According to the rounding rules included in section 5.3 of the FAO manual based on the OECD standards, the MRL should be set at 0.07 mg/kg and not rounded up at 0.1 mg/kg.

Tebuconazole (189)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities, pending the outcome of the ongoing periodic re-evaluation in the EU:

- Cumin seeds

The EU notes that an assessment strategy for triazole derivatives metabolites (TDMs) is applicable in the EU. Residue definitions for risk assessment and toxicological reference values have been revised. The EU notes that an assessment for TDMs has not been carried out for tebuconazole.

Fenpyroximate (193)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities pending outcome of the ongoing periodic re-evaluation in the EU:

- **Apple**
- **Cucumber**
- **Group of edible offal (mammalian)**
- **Group of mammalian fats (except milk fats)**
- **Group of milks**
- **Group of muscle (from mammals other than marine mammals)**
- **Subgroup of mandarins (including mandarin-like hybrids)**
- **Subgroup of oranges, sweet, sour (including orange-like hybrids)**
- **Tomatoes/Cherry tomatoes**

Based on the outcome of the ongoing evaluation, this reservation could be revised.

The EU notes some inconsistencies in the CXLs retained under the 4 years rule by CCPR 53:

- *Eggplants*: The previously derived CXL of 0.03 mg/kg which lead to an exceedance of the ARfD (160% of ARfD) was retained under the 4-years rule. Since no new GAP/data were provided, the EU requests to revoke this CXL.
- *Apples:* JMPR proposed to replace the CXLs retained under the 4-years rule by new CXLs. The EU requests to revoke the old CXLs.

The existing CXL for stone fruit needs to be revoked as recommended by JMPR in 2017.

Tebufenozide (196)

The EU **supports** the advancement of the proposed draft MRLs for the following commodities:

- **Group of avian edible offal**
- **Group of avian fat**
- **Group of avian muscle**
- **Group of edible offal (mammalian)**
- **Group of eggs**
- **Group of mammalian fats (except milk fats)**
- **Group of milks**
- **Group of muscle (from mammals other than marine mammals)**
- **Rice, husked**

Fipronil (202)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities:

- **Banana**
- **Barley, similar grains, and pseudocereals with husks, subgroup of**
- **Cotton seed**
- **Dry beans, subgroup of (except soya beans)**
- **Dry peas, subgroup of**
- **Group of avian, edible offal of**
- **Group of avian fats**
- **Group of avian muscle**
- **Group of edible offal (mammalian)**
- **Group of eggs**
- **Group of mammalian fats (except milk fats)**
- **Group of milks**
- **Group of muscle (from mammals other than marine mammals)**
- **Leafy vegetables, group of**
- **Maize cereals, subgroup of**
- **Onion, bulb**
- **Potato**
- **Rice, husked**
- **Root and tuber vegetables, group of (except potato and sugar beet)**
- **Soya bean (dry)**
- **Sugar beet**
- **Sugar cane**
- **Sunflower seeds, subgroup of**
- **Tomato, subgroup of**
- **Wheat, similar grains, and pseudocereals with husks, subgroup of**

A chronic consumer risk has been identified for European consumers accounting for 235 % of the ADI.

Spinosad (203)

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Cattle fat**
- **Cattle muscle**
- **Group of avian, edible offal of**
- **Group of avian fats**
- **Group of avian muscle**
- **Group of edible offal (mammalian) (except cattle)**
- **Group of eggs**
- **Group of mammalian fats (except milk fats) (except cattle)**
- **Group of milks (except cattle milk)**
- **Group of muscle (from mammals other than marine mammals) (except cattle)**
- **Mango**
- **Tea, green or black, fermented and dried, (including concentrates)**

Novaluron (217)

The EU **introduces a reservation** to the advancement of the proposed draft MRLs for the following commodities, due to the lack of toxicological data evaluated at EU level:

- **Group of avian, edible offal of**
- **Group of avian fats**
- **Group of avian muscle**
- **Group of edible offal (mammalian)**
- **Group of eggs**
- **Group of mammalian fats (except milk fats)**
- **Group of milks**
- **Group of tree nuts**
- **Muscle (from mammals other than marine mammals)**
- **Poultry muscle**

The EU identified in 2022 data gaps on neurotoxicity and immunotoxicity and possible endocrine disruptor properties of novaluron. Given that the last review of novaluron by JMPR was in 2005, the EU suggests that novaluron would be scheduled for periodic review.

Acibenzolar-S-methyl (228)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities pending the outcome of the revision of existing EU MRLs considering new toxicological data available:

- **Cardoon**
- **Celery**
- **Fennel, bulb**
- **Apple**
- **Rhubarb**
- **Group of muscle (from mammals other than marine mammals)**
- **Group of mammalian fats (except milk fats)**
- **Group of edible offal (mammalian)**
- **Group of milks**
- **Group of avian, edible offal of**
- **Group of avian fats**
- **Group of avian muscle**
- **Group of eggs**

Azoxystrobin (229)

The EU **supports** the advancement of the proposed draft MRLs for the following commodities:

- **Avocado**
- **Fruiting vegetables, cucurbits, except melons and watermelons**
- **Group of avian, edible offal of**
- **Group of avian fats**
- **Group of avian muscle**
- **Group of edible offal (mammalian)**
- **Group of eggs**
- **Group of mammalian fats (except milk fats)**
- **Group of milks**
- **Group of muscle (from mammals other than marine mammals)**
- **Hops, dried**
- **Melon**
- **Pineapple**
- **Watermelon**

The EU would like to ask that for reasons of transparency, the updated dietary burden calculation should be provided in Annex 6 of the JMPR report.

Cyproconazole (239)

The EU **introduces a reservation** to the advancement of the proposed draft MRLs for the following commodities:

- **Group of muscle (from mammals other than marine mammals)**
- **Group of mammalian fats (except milk fats)**
- **Group of milks**
- **Group of edible offal (mammalian)**
- **Group of avian muscle**
- **Group of avian fats**
- **Group of avian, edible offal of**
- **Group of eggs**

For products of animal origin, an updated dietary burden calculation is needed since the methodology has changed since 2021. In addition, details of the calculations are not presented in Annex 5 of the 2024 JMPR report.

The EU notes that an assessment strategy for triazole derivatives metabolites (TDMs) is applicable in the EU. Residue definitions for risk assessment and toxicological reference values have been revised. The EU notes that an assessment for TDMs has not been carried out for cyproconazole.

Flubendiamide (242)

The EU **introduces a reservation** the advancement of the proposed draft MRLs for the following commodities:

- **Group of edible offal (mammalian)**
- **Group of mammalian fats (except milk fats)**
- **Group of milks**
- **Group of muscle (from mammals other than marine mammals)**

As the model for dietary burden calculation has changed, a new dietary burden calculation should be performed according to the current methodology to derive the MRL proposals.

Acetamiprid (246)

The EU **supports** the advancement of the proposed draft MRLs for the following commodities:

- **Mung beans (dry)**
- **Subgroup of dry beans, except soya beans and mung beans**
- **Subgroup of dry peas**

Flupyradifurone (285)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities:

- **Group of avian, edible offal of**
- **Group of avian fats**
- **Group of avian muscle**
- **Group of edible offal, mammalian**
- **Group of eggs**
- **Group of mammalian fats (except milk fats)**
- **Group of milks**
- **Group of muscle (from mammals other than marine mammals)**

Since the Codex MRL proposals are not compatible with the EU Residue definition for enforcement.

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Olives for oil production**
- **Rape seeds**
- **Table olives**

Phosphonic acid (301)

Fosetyl-Al (302)

The EU **supports** the advancement of the proposed draft MRLs for the following commodities:

- **Group of avian, edible offal of**
- **Group of avian fats**
- **Group of avian muscle**
- **Group of edible offal (mammalian)**
- **Group of eggs**
- **Group of mammalian fats (except milk fats)**
- **Group of milks**
- **Group of muscle (from mammals other than marine mammals)**
- **Subgroup of oranges, sweet, sour**

The EU would like to inform JMPR that more critical GAPs for oranges and mandarins exist at EU level, leading to MRLs of 100 mg/kg. The EU encourages the applicant to submit the data to JMPR.

Fluazinam (306)

Pydiflumetofen (309)

The EU **opposes the advancement** of the proposed draft MRLs for the following commodities:

- **Lettuce, leaf**

Short-term exposure exceedances of the ARfD were indicated by JMPR.

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities pending the outcome of the ongoing approval process at EU level:

- **Lettuce, head**
- **Coffee bean,**
- **Cotton seed,**
- **Group of avian fats**
- **Group of avian muscle**
- **Group of avian, edible offal of**
- **Group of edible offal (mammalian)**
- **Group of eggs**
- **Group of mammalian fats (except milk fats)**
- **Group of milks**
- **Group of muscle (from mammals other than marine mammals)**
- **Mango**
- **Pitaya (dragon fruit)**
- **Subgroup of cane berries**

In addition, for head lettuces an acute consumer risk has been identified for European consumers.

Tetraniliprole (324)

The EU **introduces a reservation** to the advancement of the proposed draft MRLs for the following commodities, due to the lack of toxicological data evaluated at EU level:

- **Group of avian, edible offal of**
- **Group of avian fats**
- **Group of avian muscle**
- **Group of edible offal (mammalian)**
- **Group of eggs**
- **Group of mammalian fats (except milk fats)**
- **Group of milks**
- **Group of muscle (from mammals other than marine mammals)**
- **Rice, husked**
- **Subgroup of barley, similar grains, and pseudocereals with husks**
- **Subgroup of wheat, similar grains, and pseudocereals without husks**

The information included in the 2021 JMPR monographs was insufficient to confirm the toxicological assessment and safety for EU consumers.

In addition, the EU would like to ask that for transparency purposes, the exposure calculations for metabolites assessed according to the TTC approach would be published, e.g. in a separate Annex to the JMPR report.

Acynonapyr (333)

Carfentrazone- ethyl (338)

The EU supports the JMPR decision of not setting residue definitions due the lack of representative metabolism studies.

At EU level the same metabolism studies were assessed during the peer review process and it was possible to derive residue definitions for plants because the metabolism studies were representative for EU uses

Cyclobutrifluram (339)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodity based on the lack of available toxicological data at EU level:

- **Banana**

The EU notes that the proposed CXLs is based on data from samples taken at the day of the treatment (soil drench application at the foot of the tree immediately before harvest). According to plant metabolism studies, acropetal uptake and translocation of the active substance was observed. Additionally, it cannot be excluded that some bananas are harvested later than the day of the treatment. Therefore, the EU considers that the residue trials are not reflecting the most critical situation

Fenpropidin (340)

The EU **supports** the advancement of the proposed draft MRLs for the following commodities:

- **Barley**
- **Group of avian, edible offal of**
- **Group of avian fats**
- **Group of avian muscle**
- **Group of edible offal (mammalian)**
- **Group of eggs**
- **Group of mammalian fats (except milk fats)**
- **Group of milks**
- **Group of muscle (from mammals other than marine mammals)**
- **Sugar beet**
- **Triticale**
- **Wheat**

The EU would like to inform JMPR that more critical GAPs for sugar beets, barley, triticale and wheat exist at EU level. The EU encourages the applicant to submit the data to JMPR.

The EU **introduces a reservation** to the advancement of the proposed draft MRLs for the following commodity:

- **Banana**

A risk for EU consumers was identified (ARfD exceedance of 582%).

Florpyrauxifen-benzyl (341)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities

- **Group of edible offal (mammalian)**

The Codex MRL proposals are not compatible with the EU Residue definition for enforcement. For edible offals residues above the limit of quantification were found. In the JMPR report the individual concentrations for the three analytes were not reported. Hence, without this information, it is not possible to retrieve an EU MRL.

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Maize**
- **Group of milks**
- **Group of muscle (from mammals, other than marine mammals)**
- **Group of mammalian fats (except milk fats)**
- **Group of eggs**
- **Group of avian, edible offal**
- **Group of avian muscle**
- **Group of avian fats**

Fluoxapiprolin (342)

The EU **introduces a reservation** to the advancement of the proposed draft MRLs for the following commodities, pending the outcome of the toxicological evaluation and approval process at EU level:

- **Cherry tomato**
- **Grapes**
- **Group of avian edible offal**
- **Group of avian fats**
- **Group of avian muscle**
- **Group of edible offal (mammalian)**
- **Group of eggs**
- **Group of mammalian fats (except milk fats)**
- **Group of muscle (from mammals other than marine mammals)**
- **Group of milks**
- **Onion, bulb**
- **Potato**
- **Tomato**

Agenda Item 6.2 **CX/PR 25/56/6**

CXLs for milk and milk fat

European Union Competence
European Union Vote

The European Union (EU) would like to thank the Codex Secretariat for their work to implement the decisions of CCPR.

With the view of increasing the consistency and clarity for Codex MRLs established for milk, the EU would like to suggest to modify the note to the CXL proposed by the CCPR secretariat to be added to all fat soluble pesticides for which CXLs for milk are established as follows: "**For monitoring and regulatory purposes, whole milk is to be analysed.** ***If the milk analysed has a different fat content than 4%, the MRL shall be adjusted proportionally according to the fat content of the analysed milk."***

Indeed, MRLs for milk are typically based on feeding or metabolism studies in dairy cattle or lactating goats. The fat content of cow and goat milk is relatively similar, generally ranging from 3.5% to 5%. But milk fat content can vary due to feeding practices and breeding, with certain breeds like Jersey cattle producing higher fat content milk (5%). Other species, such as sheep, buffalo, elk, and reindeer, have higher milk fat content, ranging from around 7% to over 20%. Horse and donkey milk have a lower fat content, between 1% and 2%. Pesticide residues tend to accumulate in the fat portion of milk, so milk from species with higher fat content may contain higher residue levels. Since MRLs are calculated based on milk with around 4% fat content, it's important to specify this in the CXL note.

In the EU MRL legislation, the MRLs established for milk apply to the whole product based on a fat content of 4 % by weight. Where the residue definition is marked as fat soluble, the MRL is based on raw cow milk with a fat content of 4 % by weight; for raw milk of other species the MRL value shall be adjusted proportionally according to the fat content of the raw milk of that species. **If the unchanged note in its current draft form is added to Codex MRLs, the implementation of milk CXLs into EU legislation would become practically impossible.**

Additionally, the EU notes that further discussion with the Codex Committee responsible for setting MRLs for veterinary medicinal products (CCRVDF) would be necessary to ensure a consistent approach for dual use substances.

Furthermore, the EU would like to share additional observations on CXLs established for milk for further consideration:

a) To discuss the possible deletion of the suffix 'F' from CXLs for milk

For a number of fat soluble pesticides, the CXLs for milk is flagged with the suffix 'F'. According to the explanatory notes, the suffix 'F' (following MRLs for milk) indicates that *the residue is fat soluble and MRLs for milk and milk products are derived as explained in the introductions to Volume 2 of the Codex Alimentarius. The 2004 JMPR decided that, for fat-soluble pesticides, two maximum residue levels will be estimated, if data permit: one for whole milk and one for milk fat. For enforcement purposes, a comparison can be made either of the residue in milk fat with the MRL for milk (fat) or of the residue in whole milk with the MRL for milk (for details see: Report of the JMPR 2004, "2.7 Revisited: MRLs for fat-soluble pesticides in milk and milk products", pages 24-25.*

In the 2004 JMPR report it is further elaborated that the 2004 CCPR noted that the suffix 'F' means that the specific rule for application of the MRL to the fat in milk products applies. It stated that the MRL applies to the milk as such and might therefore be determined for whole milk.

However, the suffix is not consistently added for all fat soluble pesticides for which CXLs were established for both milk and milk fat, such as: azoxystrobin, bifenazate, bifenthrin, bixafen, boscalid, broflanilide, chlorantraniliprole, chlorpyrifos-methyl, cyclaniliprole, cypermethrins, endosulfan, ethiprole, fenamidone, fipronil (see below additional comments on CXLs for cattle milk and cattle milk fat), flubendiamide, fluxapyroxad, hexythiazox, indoxacarb, isoflucypram, isopyrazam, metaflumizone, novaluron, pendimethalin, quinoxyfen, sedaxane spinetoram and spinosad.

In some cases, the suffix 'F' is added to a milk CXL although no specific MRL has been established for milk fat. This is the case for the following pesticides: aldrin/dieldrin, chlordane, DDT, diflubenzuron, deltamethrin, famoxadone, fenhexamid, fenvalerate, flumethrin (Cattle milk), heptachlor, methoprene, propargite.

Overall, the suffix 'F' seems to be implemented not consistently. To avoid ambiguities and to simplify the database, it might be better to delete the suffix 'F'. The revised note (including the clause that the milk MRL is based on milk with a fat content of 4%) would also capture the message given with suffix 'F'. It should therefore be added to all existing CXLs for milk established for fat soluble substances and to all new Codex MRLs that will be established in CCPR56 and the subsequent CCPR meetings.

b) To reconsider the existing CXLs for milk/milk fat for the following pesticides: fenazaquin, cyprodinil, piperonyl butoxide, teflubenzuron and tebufenozide.

- In the case of fenazaquin, a suffix '(fat)' is added to both the CXL for milk fats and for milk. This suffix is usually only used for meat, but not for milk.
- For cyprodinil, the CXL for milks is flagged with the suffix 'F'. In addition, a note to the CXL specifies that the MRL is calculated as 4% of the LOQ for milk fat. However, for milk fat, a specific CXL (e.g. of 0.01 mg/kg) is not established.
- For piperonyl butoxide, a CXL is set for milks (0.05 mg/kg) which is flagged with 'F'; in additional, a CXL is set for cattle milk (0.2 mg/kg) which is not flagged with 'F'. To avoid ambiguities, a note should be added to the MRL for milk, specifying that it is not applicable to cattle milk. In addition, the suffix 'F' should be either removed or set for both milk CXLs, depending on the decision whether it is necessary to maintain the suffix F.
- For teflubenzuron, a CXL is set for milk of cattle, goat and sheep (ML 0107). In the new classification, the code ML 0107 does not exist any longer. In addition, a separate CXL is set for milk fat (FM 0183), which is defined as milk fats from buffalo, camel, cattle, goat and sheep. Hence, a CXL for milk fat is in place for buffalo and camel although the CXL of milk is not applicable to buffalo and camel. The outdated code ML 0107 should be replaced and if necessary, specific MRLs should be set for milk fat for the relevant species.
- For tebufenozide, CXLs are set for cattle milk (0.05 mg/kg) and for milks (0.01*). To avoid ambiguities, a note should be added to the CXL for milks, specifying that the MRL does not apply to cattle milk.

c) Depending on the outcome of the discussion on the new CXLs for fipronil, to re-consider the existing CXLs for milk and cattle milk

For fipronil, CXLs exist for milk and milk fat (0.03 mg/kg and 0.3 mg/kg, respectively). In addition, a CXL at a different level is set for cattle milk (0.02 mg/kg). None of these CXLs is flagged with F. In the CCPR56 meeting, new Codex MRL proposals for the group of milks (0.02 mg/kg) and group of milk fats (0.3 mg/kg) will be discussed. If the new CXL for the group of milks is advanced, the existing CXL for cattle milk should be revoked and the revised note should be added to the new Codex MRL for milk. If the new Codex MRL proposal is not advanced, the contradiction between the CXL for milk and cattle milk should be addressed by a note to milk ("except cattle milk").

Agenda Item 6.3 **CX/PR 25/56/7**

MRLs for okra

The European Union (EU) would like to support the recommendations included in CX/PR 25/56/7 to seek information from Codex members and observers on ongoing activities or commitment for future activities to generate residue data for okra.

In the EU, robust consumption data for dietary risk assessment are currently not available. However, considering that okras are a food commodity traded at international level, it is important to establish scientifically reliable CXLs to facilitate trade.

Residue trials for the individual pesticides used in okra should therefore be generated within reasonable timelines.

Agenda Item 8.2 **CX/PR 25/56/10**

Mixed Competence
European Union Vote

The European Union and its Member States (EUMS) would like to thank the Electronic Working Group (eWG) on management of unsupported compounds without public health concerns scheduled for periodic review by JMPR,

chaired by Chile and co-chaired by Australia, Ecuador, and Kenya for the work on the management of the national registration of pesticide database (NRD).

The EUMS acknowledge the importance of the work undertaken and the challenges encountered with the overall low participation rate. The EUMS support the recommendation to suspend the NRD-related work until it becomes necessary to support specific requests for information on unsupported compounds with no public health concern.

Agenda Item 10 **CX/PR 25/56/12**

Enhancement of the operational procedures of CCPR and JMPR

European Union Competence
European Union Vote

The European Union (EU) would like to thank the Electronic Working Group (eWG) chaired by United States of America and co-chaired by Costa Rica and Uganda for the preparation of the recommendations on the enhancement of work between CCPR and JMPR.

The EU generally supports the proposed short-term approaches to enhance the operational procedures of CCPR and JMPR from 2024 to 2026 and would like to provide comments on the proposed mechanism:

(i) Organization of extraordinary meetings of JMPR (ToR-i) to reduce the backlog of new use evaluations (i.e., additional MRLs for existing compounds that are neither scheduled for periodic reviews nor complete evaluation by JMPR).

Subject to the availability of experts and additional funding, the EU supports holding extraordinary JMPR meetings to reduce the workload at regular meetings.

Regarding the dossier revisions, the EU supports the JMPR prioritization plan outlined in point 2.10 of the 2024 JMPR report:

JMPR will be prioritizing dossiers for review which include several registered uses, where measurable residues are expected. Priority will also be assigned to those dossiers that are complete and address all the required residue and toxicology data outlined in the JMPR call for data.

(ii) Design and implementation of targeted projects to improve JMPR's evaluation process (ToR-ii), such as those described in Appendices I and II.

The EU stresses the need to consistently follow the rules set out in the Procedural Manual[3], specifically in the Section on Risk analysis principles applied by the Codex Committee on Pesticide Residues. This includes adhering to paragraph 241 which concerns the application of the four-year rule:

241. In this case, the four-year rule is applied when insufficient data have been submitted to confirm or amend an existing CXL. The CXL is recommended for withdrawal. However, Members/Observers may provide a commitment to JMPR and CCPR to provide the necessary data for review within four years. The existing CXL is maintained for a period of no more than four years pending the review of the additional data. A second period of four years is not granted.

Strict adherence to this rule, which would lead to the cancellation of active substances without data after four years, would contribute to reduce the evaluation backlog.

a. First example included in the Appendix II. Permanent JMPR staff

The EU is of the opinion that no further resources should be allocated to outdated compounds or to the evaluation of incomplete dossiers. The EU considers the publication of a JMPR *Guidance Document on data requirements* (see point b) or the exact implementation of the Risk analysis principles included in the procedural manual to be of a higher priority. In particular, after 25 years without a new toxicological evaluation, the compound should be removed from the system. This means that in the 25th year after the last evaluation, if no interest has been expressed by Members and Observers in the previous 10 years, CCPR should offer a final opportunity to Members and Observers to express their interest. In the following year, if interest is expressed, the 4-year rule may be applied, with no exemptions afterwards, as the substance will not have had a toxicological re-evaluation for 30 years. If no interest is expressed, the substance should be withdrawn.

b. Second example included in the Appendix II: Guidance to submitters of data to JMPR proposed by Crop Life International.

[3] **Last version available https://doi.org/10.4060/cd2280en**

The EU supports this proposal. As indicated in the document CX/PR 25/56/3, paragraph 1, 3rd sentence: *A new version of the Guidance Document on data requirements for the registration of pesticides has been endorsed by JMPM and is now awaiting publication*.

The publication of such Guidance Document would provide clear details on the administrative requirements for submitting dossiers.

(iii) Development of other potential activities that CCPR could advance without changes to the procedures and policies of FAO and WHO applicable for the operation of JMPR not considered in the short-term approach presented in Appendix I.

The application of emerging technological tools, including artificial intelligence (AI), may be considered for selected tasks, such as verifying the completeness of dossiers. In doing so, particular attention must be given to ensuring confidentiality, safeguarding data protection and avoiding the use of data for AI training purposes.

Agenda Item 11 **CX/PR 25/56/13**

Coordination of work between CCPR and CCRVDF: Joint CCPR/CCRVDF Working Group on Compounds for Dual Use – Status of work

Mixed Competence
European Union Vote

The European Union and its Member States (EUMS) would like to thank the chair and co-chairs of the joint electronic working group between the CCRVDF and CCPR for the work carried out.

The EUMS:

i. Express support to the Joint CCRVDF-CCPR EWG.

ii. Endorse scheduling a virtual session of the Joint EWG that precedes a virtual joint session of CCPR and CCRVDF.

iii. Support the encouragement of CCPR delegations to participate in the virtual joint session of CCPR and CCRVDF.

iv. Support the encouragement of CCPR delegations to liaise with CCRVDF counterparts to coordinate positions.

However, since the Codex Procedural Manual does not explicitly describe the arrangements of a joint committee, the EUMS would like to seek clarity from the Codex Secretariat as to how a virtual joint session of CCPR and CCRVDF can meet the existing Codex procedural provisions.